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Pesticide Fact Sheet Number 207: Coumaphos

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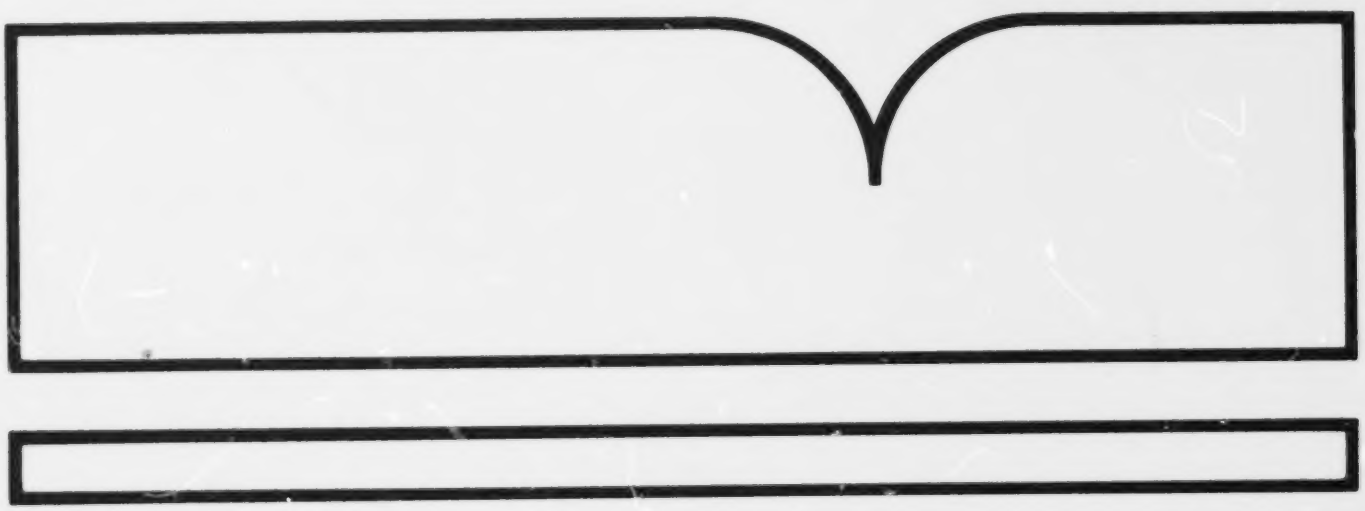

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This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

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Office of Pesticide Programs (H7508C)
Washington, DC 20460

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EPA Pesticide Fact Sheet

Name of Chemical: COUMAPHOS

Reason for Issuance: REGISTRATION STANDARD

Date Issued: SEP 27 1989

Fact Sheet Number: 207

1. DESCRIPTION OF CHEMICAL

Common Name: Coumaphos
Chemical Family: Organophosphate
Pesticide Type: Insecticide/acaricide
Chemical Name: 0,0-diethyl 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate
Trade Names: Bay 21/199, Asuntol, Muscatox, Resitox, Baymix, Meldane, Co-Ral and Negashunt
Other Chemical Nomenclature: 0-3-chloro-4-methylcoumarin-7-yl 0,0-diethyl phosphorothioate; 3-chloro-7-diethoxyphosphino-thioyloxy-4-methylcoumarin; 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) 0,0-diethyl phosphorothioate (Chemical Abstracts, 9th Collective Index); 3,chloro-7-hydroxy-4-methylcoumarin 0-ester with 0,0-diethyl phosphorothioate (8th Collective Index); O,3-chloro-4-methyl-2-oxo-2H-chromen-7-yl O-0-diethyl phosphorothioate; [0-(3-chloro-4-methyl-7-coumarinyl)] 0,0-diethyl phosphorothioate; 0,0-diethyl 0-(3-chloro-4-methyl-7-courmarinyl) phosphorothioate; phosphorothioic acid 0-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) 0,0-diethyl ester; 3-chloro-4-methylumbelliferone, 0-ester with 0,0-dietyl phosphorothioate; 0,0-diethyl 0-(3-chloro-4-methylumbelliferone thiophosphate
Year of Initial Registration: 1958
CAS Registry Number: 56-72-4
EPA Pesticide Chemical Code (Shaughnessy Number): 036501
U.S. Manufacturer: Bayvet, a division of Cutter Laboratories

USE PATTERNS AND FORMULATIONS

Coumaphos is applied as a direct animal treatment to control arthropod pests of beef cattle, dairy cattle, sheep, goats, horses and swine. It is used to treat swine bedding. Registered control claims are for face flies, horn flies, fly larvae, cattle grubs, ticks (including ear tick), lice, mites, screwworms, sheep keds and fleeceworms. Methods of application consist of dusts, sprays, dips, pour-ons, dust bags and backrubber oilers. Annual usage is 264,000 to 525,600 lbs (1986 estimate). The predominate use is on beef cattle (98%). A relatively small amount is used on dairy cattle (<2%) and swine (<1%).

Current Status and Summary Science Statement

Toxicity data requirements for registration of products containing coumaphos (including acute toxicity testing on end-use product formulations) have been met, except for a 21-day dermal toxicity study, a non-rodent chronic toxicity study, a reproduction study, and a structural chromosome aberration study. Technical coumaphos is highly acutely toxic by the oral and inhalation routes of exposure (Toxicity Category I and II, respectively) and moderately acutely toxic by the dermal route of exposure (Toxicity Category III) based on studies using rats, rabbits and guinea pigs. Technical coumaphos causes only mild eye and dermal irritation (Toxicity Category III and IV, respectively), and is nonsensitizing. End-use product formulations fall in a range of Toxicity Categories from I to III. Coumaphos does not produce organophosphate-type delayed neurotoxicity, based on acute neurotoxicity testing in hens. The oncogenic potential of coumaphos is satisfactorily defined. In vitro microbial studies for gene mutation and DNA damage coumaphos did not cause a mutagenic response, and when tested in the rat and mouse, there were no carcinogenic effects noted. Coumaphos is not a developmental toxicant, or teratogen based on findings in studies utilizing rats and rabbits. Results of a chronic feeding study using rats show that cholinesterase (plasma and erythrocyte) is the primary target of coumaphos. Decreased body weight gain is a secondary effect. In a rat metabolism study, coumaphos was rapidly excreted. There were no dose-related changes in metabolism or evidence of activation/bioaccumulation.

The coumaphos data base for ecological effects testing is complete, with the exception of two special studies. Based on the results of laboratory studies using birds, fish, and aquatic invertebrates, technical coumaphos is moderately acutely toxic to fish and very highly acutely toxic to birds and aquatic invertebrates. Coumaphos is moderately toxic to birds on a subacute (dietary) basis. Aquatic invertebrates may be potentially exposed to hazardous levels of coumaphos resulting from washing-off of the material from the backs of newly treated

cattle which have entered a body of water. Aquatic residue monitoring is required to assess the potential hazards. Due to the potential for avian exposure resulting from birds feeding in cattle lots and on the backs of cattle, Tier I avian field testing is required to assess possible effects to birds resulting from the direct treatment to livestock.

The environmental fate profile for coumaphos is adequately delineated for the registered use pattern, except for a groundwater assessment. Coumaphos is relatively immobile in aged sandy loam soil, based on findings in a column leaching study. There are no immediate concerns for groundwater contamination from non-point source application of coumaphos. However, the potential does exist for localized, point source contamination in animal treatment areas (particularly where animals are dipped), and as a result of associated disposal practices. Due to increased Agency sensitivity in the area of pesticides and groundwater contamination, environmental fate studies are required so that the Agency can assess coumaphos's potential for point source contamination.

Most of the residue chemistry conclusions drawn in the 1981 Standard have been reversed in the current Standard. Residue chemistry data requirements were not imposed in the 1981 Standard. Since issuance of that Standard, the Agency has published residue chemistry guidelines (Pesticide Assessment Guidelines, Subdivision O, 1982, EPA-540/9-82-023) and other Federal Register (FR) Notices which provide a more stringent interpretation of the existing regulations. As a result of these new guidelines, data are now required in the area of animal metabolism, storage stability and method validation. No changes to coumaphos tolerances are indicated at this time.

The Agency is unable to totally assess the safety of current tolerances and establish an acceptable daily intake (ADI) value for coumaphos because of the absence of chronic toxicity studies (reproduction and dog chronic toxicity), and outstanding residue chemistry data. However, a preliminary dietary exposure analysis has been performed for coumaphos. Based on the results of this analysis, current coumaphos tolerances are considered to be adequate to protect the public health. When the remaining data requirements have been fulfilled, the Agency will perform a final reassessment of coumaphos tolerances.

Chemical/Physical Characteristics of the Technical Material

Empirical Formula: $C_{14}H_{16}ClO_5PS$
Molecular Weight: 362.8
Color: grey to tan
Physical state: powder to granules
Odor: characteristic sulfur
Melting Point: 90 to 95 °C

Boiling Point: 20 °C at 10^{-7} mmHg

Solubility: (at 20 °C): g/100 mL at 20 C

acetone	23.82
methylene chloride	6.39
denatured alchohol	0.90
xylenes	0.90
hexanes	0.07
water insoluble at	0.002
octanol	0.13
odorless mineral spirits	0.09
diethyl phthalate	21.50

Vapor Pressure: 1 X 10^{-7} mmHg

Density, Bulk Density, or **Specific Gravity:** granules: 30.06 lb/cu ft, loose; 30.85 lb/cu ft, packed. mhammermilled: 24.35 lb/cu ft, loose; 30.51 lb/cu ft, packed

pH: 7.23 at 1 g/100 mL

Stability: hydrolyses slowly under alkaline conditions; stable under normal storage conditions and use; incompatible with piperonyl butoxide

Storage Stability: Stable (<6% loss) in glass vials up to 8 weeks at -12 to 50 C, dry and at pH 4-10, at 83% moisture, exposed to aluminum, and stainless steel; stable exposed to sunlight for 4 days.

Toxicology Characteristics

Acute Oral: Toxicity Category I (LD_{50} of greater than 240 mg/kg in males rats and 17 mg/kg in female rats)

Acute dermal: Toxicity Category III (LD_{50} of greater than 2400 mg/kg in rabbits

Acute inhalation: Toxicity Category II (LC_{50} dose for a 1-hour is 341 mg/m^3 in female rats and greater than 1080 mg/m^3 in male rats)

Primary eye irritation: Toxicity Category III, mild eye irritation reported

Primary dermal irritation: Toxicity Category IV, very minor dermal irritation reported

Skin sensitization: No observable evidence of dermal sensitization

Delayed Neurotoxicity: Did not induce delayed neurotoxicity in an acceptable study in hens.

Subchronic non-rodent/ rodent studies: None available. Not required since chronic data supercede need for subchronic testing.

21-day dermal toxicity: Required Study

Chronic toxicity: Dog study is required. Rat study NOEL is 0.07 mg/kg for decreased cholinesterase activity.

Oncogenicity: The mouse and rat chronic toxicity/ oncogenicity studies did not reveal any evidence that coumaphos is oncogenic.

Mutagenicity: Negative in all areas of mutagenicity tested. A structural chromosomal abberation study is required.

Teratogenicity: Rat teratology study NOEL and LEL were 5 and 25 mg/kg (based on the observation of cholinergic effects), respectively. The developmental NOEL was greater than 25 mg/kg (HDT). Rabbit teratology study maternal NOEL and LEL were 2.0 and 18.0 mg/kg, respectively; developmental NOEL was greater than 18.0 mg/kg (HDT).

Reproduction: Required study

Metabolism: In a rat metabolism study, coumaphos was rapidly excreted. No dose-related changes in metabolism or evidence of activation/bioaccumulation were noted in this study.

Environmental Characteristics

Based on the results of a column leaching study, coumaphos can be characterized as persistent, but immobile in sandy loam soils. There are no immediate concerns for groundwater contamination from non-point source application of coumaphos. However, the potential does exist for localized, non-point source contamination in animal treatment areas (particularly where animals are dipped), and as a result of associated disposal practices. In order to evaluate the potential for point source contamination, special studies are required: a photodegradation study in soil, a photodegradation study in water, an adsorption/desorption study, a hydrolysis study and a retrospective field dissipation study.

Ecological Characteristics

Based on the results of acceptable laboratory data, technical coumaphos is characterized as highly to very highly toxic to birds, moderately toxic to fish and highly toxic to aquatic invertebrates:

- Acute LD_{50} (mallard): 29.4 mg/kg
- Acute LD_{50} (pheasant): 7.94 mg/kg
- Dietary LC_{50}:
  401 ppm (mallard)
  82 ppm (bobwhite)
- Freshwater invertebrates toxicity (96-hr LC_{50}) for amphipods: 0.15 ppb
- Fish acute toxicity (96-hr LC_{50}) for rainbow trout: 5900 ppb
- Fish acute toxicity (96-hr LC_{50}) for bluegill sunfish: 5000 ppb

Results of laboratory testing, in conjunction with theoretical monitoring, indicate that aquatic invertebrates may be potentially exposed to hazardous levels of coumaphos resulting

from washing-off of the material from the backs of newly treated cattle which have entered a body of water, such as a pond or stream. To evaluate the potential risk, a residue monitoring study is required. There is a potential for avian exposure resulting from birds feeding in cattle feedlots and on the backs of cattle. Tier I avian field testing is required to assess possible effects to birds resulting from direct treatment to livestock.

Tolerance Assessment

U.S. tolerances are established for residues of the insecticide coumaphos, O,O-diethyl O-(3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl) phosphorothioate, and its oxygen analog, O,O-diethyl O-3-chloro-4-methyl-2-oxo-2H-1-benzopyran-7-yl-phosphate, in or on raw agricultural products as follows (40 CFR 180.189):

- o 1 ppm in or on meat, fat, and meat byproducts of cattle, goats, hogs, horses, poultry[1], and sheep
- o 0.5 ppm in milk fat (reflecting negligible residues in milk)
- o 0.1 ppm in eggs

Most of the residue chemistry conclusions drawn in the 1981 Standard have been reversed. No residue chemistry data requirements were imposed in the 1981 Standard. Since issuance of that Standard, the Agency has published residue chemistry guidelines (Pesticide Assessment Guidelines, Subdivision O, 1982, EPA-540/9-82-023) and other FR Notices which provide a more stringent interpretation of the existing regulations. As a result of these new guidelines, data are now needed in the area of animal metabolism, storage stability and method validation.

The Provisional Acceptable Daily Intake (PADI) for coumaphos is 0.0007 mg/kg/day and is based on the 2-year rat feeding/oncogenicity study NOEL of 0.07 mg/kg/day (based on plasma cholinesterase inhibition in females) and uncertainty factor of 100. The Anticipated Residue Contribution (ARC) for the United States population is 0.000127 mg/kg/day, occupying 18.2% of the PADI. The two highest calculated exposures for the population subgroups are children 1 to 6 years of age [ARC occupies 33.6% of the PADI] and children 7 to 12 years of age [ARC occupies 25.6% of the PADI]. Based on these calculations, coumaphos applied at the currently registered application rates would not be expected to exceed established tolerances.

The Agency is unable to totally assess the safety of current tolerances and establish an acceptable daily intake (ADI) value for coumaphos because of the absence of chronic toxicity studies (reproduction and dog chronic toxicity), and outstanding data in

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[1] There are no longer any federally registered uses for poultry/poultry houses. Therefore, the Agency intends to revoke the tolerances for poultry and eggs.

the area of animal metabolism, method validation and storage stability. When the required data have been submitted and evaluated, the Agency will perform a final reassessment of coumaphos tolerances.

4. SUMMARY OF REGULATORY POSITIONS AND RATIONALES

- The Agency is not initiating a Special Review for coumaphos. No Special Review concerns were identified for this chemical by the Agency during its review of the current data base.

- The Agency is classifying coumaphos 11.6% EC and 42% flowable concentrate end-use products as restricted use due to acute oral hazards.

- The Agency will approve new food/feed tolerances for coumaphos on a case-by-case basis.

- Environmental fate testing is required to evaluate the potential for coumaphos to impact groundwater or surface water resulting from point source application.

- A special aquatic residue monitoring study is required.

- Special Tier I avian field testing is required.

- The Agency will revoke the poultry and egg tolerances, since coumaphos is no longer federally registered for use on poultry or in poultry houses.

- Unique labeling statements are required:

o Restricted-use classification is required for coumaphos 11.6% EC and 42% flowable concentrate formulations.

o Special disposal instructions are required for products bearing directions for use a livestock dip treatment.

o Labels bearing directions for use on goats and sheep must be amended to specify a preslaughter interval (PSI) of 3 days.

o Product labels must bear revised and updated fish and wildlife statments.

o Worker safety and protective clothing statements are required for products falling in Toxicity Category I or II.

o Each end-use product label must be revised to reflect the appropriate signal word and precautionary statements assigned to it based on the results of acceptable acute toxicity testing.

o Revised labeling must be submitted for those products which do not contain directions for use specifying a maximum single application rate expressed in terms of: (1) amount of

active ingredient per animal; (2) a maximum seasonal application rate or number of applications permitted per season; and (3) a minimum interval between applications, revised labeling must be submitted.

SUMMARY OF OUTSTANDING DATA REQUIREMENTS

Toxicology

21-Day Dermal Toxicity	1 Year
Dog Chronic Toxicity	4 Years
Reproduction Study	4 Years
Chromosome Aberration	1 Year

Environmental Fate/Exposure

Photodegradation in Water and Soil	1 Year
Adsorption/Desorption	2 Years
Special Retrospective Field Dissipation Study	2 "
Hydrolysis Study	1 "

Fish and Wildlife

Monitoring for Aquatic Invertebrate Mortality and Residues in Water	3 Years
Tier I avian field testing	3 Years

Residue Chemistry

Metabolism data - Animals	1 Years
Residue Analytical Methods	1 "
Storage Stability Data	1 "

Product Chemistry

Remaining Data Gaps	1 -2 Years

6. Contact Person at EPA

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